

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Terence D. Butters, et al.

Confirmation No.: Not Yet Assigned

Application No.: 10/618,165

Group Art Unit: Not Yet Assigned

Filing Date: July 11, 2003

Examiner: Not Yet Assigned

For: PHARMACEUTICALLY ACTIVE PIPERIDINE DERIVATIVES

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		they were previously cited by or submitted to the U.S. Patent and					
		Trademark Office in patent application(s) for which a claim for priority					
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□ The relevance of those listed references which are not in the English language is as follows:
 □ English language abstracts have been provided for references 28 and 29 which are not in the English language.

Date: December 10, 2003

DOCKET NO.: OGS-0002/P0055-USW01-4-

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PATENT



Form PTO-1449 Modified	Docket No. OGS-0002/ P0055-USw01	Application No. 10/618,165			
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)	Applicant Terence D. Butters, et al.				
U.S. Department of Commerce Patent and Trademark Office	Filing Date July 11, 2003	Group Not Yet Assigned			
	Confirmation No. Not Yet Assigned				
OTHER DOCUMENTS (Included)	ding Author, Title, Da	te, Pertinent Pages, Etc.)			
substrate deprivation," J	mide in fabry disease mice by 2000 , <i>105(11)</i> , 1563-1571 tors from the bark of <i>angylocalyx</i> 1 , <i>268</i> , 35-41				
-	deoxymannojirimycin, deoxyaltrojirimycin and deoxygalactostatin," Chem.				
diastereoselective appro-					
amination of dicarbonyl	amination of dicarbonyl sugars," J. Org. Chem., 1994, 59, 3175-3185				
aminoalditols total synth					
* 7 Biochemical Genetics, A	A Laboratory Manual, C	Oxford University Press			
	mucolipidosis, type IV disease," Proc. Natl. Acad. Sci. USA, May 1998, 95,				
9 Cox, T., et al., "Novel oral treatment of gaucher's disease with N-butyldeoxynojirimycin (OGT 918) to decrease substrate biosynthesis," <i>The</i> April 29, 2000 , <i>355</i> , 1481-1485					
	al., "Lipophilic prodrugs of 1-deoxynojirimycin derivatives," etts., 2000, 41, 7313-7315				
EXAMINER	DATEC	ONSIDERED			

^{*} A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.



Form PTO-1449 Modified List of Patent and Publications Docket No. OGS-0002/ P0055-USw	10/618 165				
List of Datant and Publications	/01				
Cited by Applicant Applicant					
U.S. Department of Commerce Patent and Trademark Office Filing Date July 11, 200					
Confirmation Not Yet As					
OTHER DOCUMENTS (Including Author,	Title, Date, Pertinent Pages, Etc.)				
Fowler, P.A., et al., "Synthesis and ac dideoxy-1,5 imino-L-iditol (1-deoxy-246, 377-381	ctivity towards yeast α-glucosidase of 1,5- L-idonojirimycin)," Carbohydrate Res., 1993,				
Godskesen, M., et al., "Deoxyiminoal the four stereoisomers of 1,5-dideoxy	inoalditols from aldonolactones – V. preparation of eoxy-1,5-iminopentitols. Evaluation of these eoxy-1,5-iminoheptitols as glycosidase inhibitors," 1996, 4(11), 1857-1865				
13 Goodman, L.A., et al., "Ectopic dends containing elevated GM2 ganglioside USA, December 1991, 88, 11330-113	rites occur only on cortical pyramidal cells in α-mannosidosis," <i>Proc. Natl. Acad. Sci.</i> 34				
amino acid ester enolates," Tetrahedr	of azasugars via aldol reaction of chelated on Letts., 1997, 38(46), 8009-8012				
* Greene, et al., Protective Groups in O NY, 1991					
Hügel, H.M., et al., "Stereoselective of derived from carbohydrates: synthesis 1998, 51, 1149-1155	derived from carbohydrates: synthesis of polyhydroxypiperidines," Aust. J. Chem.,				
Ikota, N., et al., "Improved synthesis its stereoisomers from (S)-pyroglutan 637-643	Ikota, N., et al., "Improved synthesis of 1-deoxynojirimycin and facile synthesis of its stereoisomers from (S)-pyroglutamic acid derivative," <i>Heterocycles</i> , 1997 , <i>46</i> , 637-643				
sandhoff disease mice treated with N- USA, May 1999, 96, 6388-6393	l., "Delayed symptom onset and increased life expectancy in ce treated with <i>N</i> -butyldeoxynojirimycin," Proc. <i>Natl. Acad. Sci.</i> , 6388-6393				
azido sugars prepared from enzymati	Kajimoto, T., et al., "Palladium-mediated stereocontrolled reductive amination of azido sugars prepared from enzymatic adol condensation: a general approach to the synthesis of deoxy aza sugars," J. Am. Chem. Soc., 1991, 113, 6678-6680				
	Kazmaier, U., et al., "A short synthesis of polyhydroxylated piperidines by adol reaction of chelated amino acid ester enolates," Eur. J. Org. Chem., 1998, 1833-1840				

^{*} A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.



	Form PTO-1449 Modified		Docket No OGS-0002 P0055-US	/	Application No. 10/618,165	
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11.0.5						
	U.S. Department of Commerce Patent and Trademark Office			e 003	Group Not Yet Assigned	
				on No. ssigned		
OT	THE	R DOCUMENTS (Includ	ing Author	, Title, Date, I	Pertinent Pages, Etc.)	
	21	Lee, B.W., et al., "A short and efficient synthesis of 2R,3R,4R-3,4-dihydroxyproline, 1,4-dideoxy-1,4-imino-L-xylitol, 2R,3R,4R,5S-3,4,5-trihydroxypipecolic acid, and 1,5-dideoxy-1,5-imino-L-iditol," <i>Synthesis</i> , 2000 , <i>9</i> , 1305-1309				
	22				tent inhibitors of glycosidases,"	
		Bioorganic & Medicinal Chem., 1997, 5(3), 519-533				
	23	· · · · · · · · · · · · · · · · · · ·				
		endocellulases," J. Am. C				
	24					
		glucosylceramide synthase antisense reverses adriamycin resistance," <i>J. of Biol. Chem.</i> , March 10, 2000 , <i>275(10)</i> , 7138-7143				
	25	Lundt, I., et al., "Deoxyiminoalditols from aldonolactones; IV: preparation of 1,5-				
	dideoxy-1,5-iminoheptitols with L-glycero-D-manno, D-glycero-L-gulo an					
	26	glycero-D-altro configur				
	Mehta, G., et al., "A norbornyl route to azasugars: a new synthesis of deoxynojirimycin analogues," <i>Tetrahedron Letts</i> , 2000 , <i>41</i> , 5741-5745				-	
	27					
	Mellor, H.R., "High-performance cation-exchange chromatography and pulsed amperometric detection for the separation, detection, and quantitation of N-alkyla imino sugars in biological samples," <i>Analytical Biochemistry</i> , XP-001055984, 20 (284, 136-142)				n, and quantitation of N-alkylated	
	28	Ber., 1967, 100, 512-520 (German language); Chemical Abstracts #3208 "Thymine				
	nucleosides of 3-deoxy-d-xylo-hexose," page 3207					
	29	Paulsen, H., et al., "Synthese und reaktionen von keto-piperidinosen," <i>Chem. Ber.</i> , 1967, 100, 802-815 (English Abstract)				
	30					
EXAMINER				DATE CONS	SIDERED	
	DATE CONSIDERED					



	-1449 Modified	Docket No. OGS-0002/ P0055-USw01	Application No. 10/618,165		
Cited b	t and Publications y Applicant heets if necessary)	Applicant Terence D. Butters, et al.			
	nent of Commerce Trademark Office	Filing Date July 11, 2003	Group Not Yet Assigned		
		Confirmation No. Not Yet Assigned			
OTHER	R DOCUMENTS (Incl	uding Author, Title, Dat	te, Pertinent Pages, Etc.)		
31	Platt, F.M., et al., "Prevention of lysosomal storage in tay-sachs mice treated w butyldeoxynojirimycin," <i>Science</i> , April 18, 1997 , 276, 428-431				
32	piperidines," Tetrahed	ron Letts., 1996, 37(10),			
33	Rao, V.S., et al., "Regioselective eliminations in reactions of carbohydrate derivatives with superoxide, or with borohydride in 2-propanol," Can. J. Chem., 1981, 59, 333-338 Reitz, A.B., et al., "Pyrrolidine and piperidine aminosugars from dicarbonyl sugars one step. Concise synthesis of 1-deoxyojirimycin," Tetrahedron Letts., 1990, 31(4): 6777-6780 Schaller, C., et al., "Total synthesis of (+)- and (-)-1-deoxynojirimycin (1,5-dideox 1,5-imino-D- and L-glucitol) and of (+)- and (-)-1-deoxyidonojirimycin (1,5-dideoxy-1,5-imino-D- and L-iditol) via furoisoxazoline-3-aldehydes," Carbohydra Res., 1998, 314, 25-35				
34					
35					
36		actional rafts in cell membranes," Nature, June 5, 1997, 387,			
Subramanian, T., et al., "Synthesis of oxazolidinyl azacycles via ring-closing of metathesis: a practical entry to the synthesis of deoxy-azasugars and hydroxypyrrolizidines," <i>Tetrahedron Letts.</i> , 2001 , <i>42</i> , 4079-4082					
38	Uriel, C., et al., "A short and efficient synthesis of 1,5-dideoxy-1,5-imino-D-galactitol (1-deoxy-D-galactostatin) and 1,5-dideoxy-1,5-imino-L-altritol (1-deoxy-L-altrostatin) from D-galactose," Synlett, 1999, 5, 593-595				
39	Xu, YM., et al., "A new approach to 1-deoxy-azasugars: asymmetric synthesis of 1-deoxymannojirimycin and 1-deoxyaltronojirimycin," J. Chem. Sco. Perkin Trans., 1997, 1, 741-746				
EXAMINER		DATE CO	ONSIDERED		



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				Confirmation No. Not Yet Assigned			
		FORE	IGN PATI	ENT DOCUMENTS			
Examiner Initial		Document No.	Date	Country		Transl YES	lation NO
	40	0 536 402 A	04/14/93	EPO			
	41	3-24057	02/01/91	Japanese		X abstract	
	42	WO 94/26714	11/24/94	PCT			
	43	WO 98/02161	01/22/98	PCT			
	44	WO 01/10429 A2	02/15/01	PCT			
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